K011560

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
~~Fax (717) 849-4762~~

JUL 1 2 2001

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 18, 2001

TRADE OR PROPRIETARY NAME: TRUBYTE® DENTURE BASE RESIN SYSTEM

CLASSIFICATION NAME: Relining, Repairing and Rebasing Resin 872.3670

PREDICATE DEVICES:

TRIAD® Denture Base	K831647
TRIAD® Reline Material	K834409

DEVICE DESCRIPTION: The TRUBYTE® DENTURE BASE RESIN SYSTEM is composed of four resin formulations: Denture Baseplate Resin, Set-up Resin, Contour Resin, and Clear Resin. The finished denture base is constructed from a laminate of these resins that are light cured. These new materials bypass the usual "lost wax" process and allow the dentist and technician to develop a trial denture that will become the final denture. It will not be necessary to fabricate a mold or "invest" the trial denture.

INTENDED USE: 1) Fabrication of dentures, appliances and prostheses; 2) Repair of dentures, appliances and prostheses; and 3) Relining of denture surfaces.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the Resins of the TRUBYTE® DENTURE BASE RESIN SYSTEM have been used in legally marketed devices or were found safe for dental use.

The TRUBYTE® DENTURE BASE RESIN SYSTEM resins, uncured and cured, have been evaluated and passed biocompatibility testing for cytotoxicity, mutagenicity, irritation, and sensitization.

We believe that the prior use of the components of TRUBYTE® DENTURE BASE RESIN SYSTEM in legally marketed predicate devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of TRUBYTE® DENTURE BASE RESIN SYSTEM for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Mr. P. Jeffery Lehn
Director of Corporate Compliance & Regulatory Affairs
Dentsply International
570 West College Avenue
York, Pennsylvania 17404

Re: K011560
Trade/Device Name: Trubyte® Denture Base Resin System
Regulation Number: 872.3760II
Regulatory Class: II
Product Code: EBI
Dated: May 18, 2001
Received: May 21, 2001

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Rebecca Cucente/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT K011560

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K011560

Device Name: **TRUBYTE® DENTURE BASE RESIN SYSTEM**

Indications for Use:

1. Fabrication of dentures, appliances and prostheses
2. Repair of dentures, appliances and prostheses
3. Relining of denture surfaces

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(K) Number K011560